

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/402,614	03/01/00	RISBRIDGER	G 229752000806

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755 PAGE MILL ROAD  
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EXAMINER	
NICKOL, G	
ART UNIT	PAPER NUMBER
1642	
DATE MAILED: 03/09/01	

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/402,614	RISBRIDGER ET AL.
	Examiner Gary B. Nickol Ph.D.	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-26 and 40-67 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_ is/are allowed.  
 6) Claim(s) \_\_\_\_ is/are rejected.  
 7) Claim(s) \_\_\_\_ is/are objected to.  
 8) Claims 1-26, 40-67 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.  
 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved.  
 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.  
 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- 15) Notice of References Cited (PTO-892)                  18) Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
 16) Notice of Draftsperson's Patent Drawing Review (PTO-948)                  19) Notice of Informal Patent Application (PTO-152)  
 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_                  20) Other: *fax sheet*.

## DETAILED ACTION

Claims 1-26, 40-67 are pending in the application and are currently under prosecution.

**Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Anthony Caputa, Ph.D., Supervisory Patent Examiner at 703-308-3995. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-6,14-19 drawn to a method of modulating cell growth comprising administering an agent to modulate the expression of a genetic sequence encoding inhibin.

Group 2, claim(s) 7-11,20-24 drawn to a method of modulating cell growth comprising administering an effective amount of inhibin.

Group 3, claim(s) 12-13, 25-26 drawn to a method of modulating cell growth comprising administering an effective amount of an inhibin antagonist.

Group 4, claim(s) 40-45, 53-54 drawn to an agent for use in modulating the expression of a genetic sequence encoding inhibin.

Group 5, claim(s) 46-50, 55-56 drawn to an agent for use in the modulation of cell growth in a mammal comprising inhibin.

Group 6, claim(s) 51-52,57 drawn to an agent for use in the modulation of cell growth in a mammal comprising an inhibin antagonist.

Group 10, claim(s) 58,60-63, drawn to a method of screening for a mammal **as specifically drawn to having prostate cancer**, comprising screening for the down-regulation of inhibin protein levels wherein said levels are indicative of said mammal having already developed cancer.

Group 11, claim(s) 58,60-63, drawn to a method of screening for a mammal **as specifically drawn to predisposition to prostate cancer**, comprising screening for the down-regulation of inhibin protein levels wherein said levels are indicative of said mammal being predisposed to prostate cancer.

Group 12, claim(s) 59-63, drawn to a method of screening for a mammal **as specifically drawn to having prostate cancer**, comprising screening for the down-regulation of inhibin gene expression wherein said down-regulation is indicative of said mammal having already developed cancer.

Group 13, claim(s) 59-63, drawn to a method of screening for a mammal **as specifically drawn to predisposition to prostate cancer**, comprising screening for the down-regulation of inhibin gene expression wherein said down-regulation is indicative of said mammal being predisposed to prostate cancer.

Group 14, claim(s) 64-65, drawn to a method of screening for a mammal having prostate cancer, comprising screening for the down-regulation of  $\alpha$ -subunit gene expression.

Group 15, claim(s) 66, drawn to a method of screening for a mammal having a predisposition to prostate cancer, comprising screening for  $\alpha$ -subunit gene expression wherein said expression reveals disruption of the basement membrane.

Group 16, claim(s) 67, drawn to a method of screening for a mammal **as specifically drawn to having prostate cancer**, comprising screening for the modulation of activin protein wherein said modulation is indicative of said mammal having already developed cancer.

Group 17, claim(s) 67, drawn to a method of screening for a mammal **as specifically drawn to predisposition to prostate cancer**, comprising screening for the modulation of activin protein wherein said modulation is indicative of said mammal being predisposed to prostate cancer.

The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Unity of invention is fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding special technical features which define a contribution over the prior art. If there is no special technical feature, if multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(d).

The inventions listed as Groups 1-17 do not relate to a single inventive concept under PCT Rule 13.1 because under PCT Rule 13.2 they lack the same or corresponding special technical features for the follow reason:

The technical feature linking groups 1-17 appears to be methods for modulating cell growth in a mammal comprising administering an agent sufficient to modulate the expression of inhibin.

However, Alvarado et al. (J Histochem. Cytochem. Vol 41, No.1, 1993, abstract only) teach a method for modulating cell growth (mammary) in a mammal by administering an agent (hCG) which modulates the expression of inhibin. Therefore, the technical feature linking the inventions of groups 1-17 does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. According Groups 1-17 are not so

linked by the same or a corresponding special technical feature as to form a single general inventive concept and restriction for examination purposes as indicated is proper.

**Species Election.**

Groups 10-13 (Claims 61 and 62) are generic to a plurality of disclosed patentably distinct species comprising the following:

- (a)  $\alpha$ -inhibin is a  $\alpha$ N or isoform thereof (Claim 61)
- (b)  $\alpha$ -inhibin is a  $\alpha$ C or isoform thereof (Claim 62)

The products of the above species represent separate and distinct molecules with different structures and functions such that one species could not be interchanged with the other. As such, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 703-305-7143. The examiner can normally be reached on M-F, 8:30-5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary B. Nickol, Ph.D.  
Examiner  
Art Unit 1642

GBN  
March 7, 2001

*Susan Ungar*  
SUSAN UNGAR, PH.D  
PRIMARY EXAMINER

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